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Cardiac Adverse Events Following Smallpox Vaccination — United States, 2003

During January 24–March 21, smallpox vaccine was administered to 25,645 civilian health-care and public health workers in 53 jurisdictions as part of an effort to prepare the United States in the event of a terrorist attack using smallpox. Seven cases of cardiac adverse events have been reported among civilian vaccinees since the beginning of the smallpox vaccination program. In addition, 10 cases of myopericarditis have been reported among military vaccinees. This report summarizes data on the seven cases reported among civilians and provides background information on recent military vaccinees. Although a causal association between vaccination and adverse cardiac events in the civilian population is unproven, as a precautionary measure, CDC recommends that persons with physician-diagnosed cardiac disease with or without symptoms (e.g., previous myocardial infarction, angina, congestive heart failure, or cardiomyopathy) be excluded from vaccination during this smallpox preparedness program.

CDC, the Food and Drug Administration, and state health departments are conducting surveillance for vaccine-associated adverse events among civilian vaccinees; the Department of Defense (DoD) is conducting surveillance for vaccine-associated adverse events among military vaccinees.

In the first stage of the civilian program, active surveillance is being conducted for any adverse events after vaccination that require medical care. Cardiac adverse events among civilians and myopericarditis cases among military vaccinees were reported to CDC from the Vaccine Adverse Event Reporting System (VAERS) as of March 23. Four of the civilian cases were previously reported in *MMWR*. Reported adverse events are not necessarily associated causally with vaccination, and some or all of these events might be coincidental.

The seven adverse events of cardiac origin among civilian vaccinees include three myocardial infarctions, two cases of angina, and two cases of myopericarditis. The median age of patients was 50 years (range: 43–60 years), and five were women. Two of the three patients who had a myocardial infarction died. Two had previous illnesses consistent with coronary artery disease (CAD); the other had a history of hypertension, a known risk factor for CAD. Of the two patients with angina, one had a history of CAD, and the other had no history of CAD but at cardiac catheterization was discovered to have a tortuous coronary artery. Both patients with myopericarditis had a history of hypertension but no history of CAD. The five patients with myocardial infarction and angina had illness onset from 4 to 17 days after vaccination; the two patients with myopericarditis were both aged 45 years and had onset of illness at 2 and 17 days after vaccination.

Case Reports

Case 1. A woman aged 50 years with a history of hypertension, hypercholesterolemia, and smoking was vaccinated on March 18, 2003. On March 22, she had chest tightness, dizziness, nausea, and vomiting; approximately 24 hours after onset of these symptoms, she was found unresponsive and pronounced dead. A preliminary autopsy report indicated that a myocardial infarction with thrombus of the right coronary artery had occurred with extensive underlying atherosclerotic disease.

Case 2. On March 4, a woman aged 57 years with a history of smoking and hypertension reported to an emergency department (ED) and was diagnosed with an exacerbation of chronic obstructive pulmonary disease and dehydration 6 days after smallpox vaccination (*1*). The patient had a previous cardiac catheterization that was complicated by a transient ischemic attack during the procedure. In the ED, she was treated with oxygen, antibiotics, and intravenous fluids and was released. On March 16, the patient was hospitalized again following a sudden cardiopulmonary arrest at home. Approximately 10–20 minutes elapsed between the time of the arrest and the arrival of emergency medical personnel. The patient was admitted to a cardiac intensive care unit with a diagnosis of myocardial infarction. The patient died on March 26.

Case 3. A woman aged 54 years with a history of poorly controlled diabetes mellitus, hypertension, obesity, untreated hyperlipidemia, and a recent history of exertional chest pain was vaccinated on March 3. On March 12, she had onset of chest discomfort and irregular heartbeat. She was hospitalized with atrial fibrillation and had electrocardiographic changes and elevated cardiac enzymes consistent with subendocardial myocardial infarction. Cardiac catheterization indicated severe CAD. Echocardiography showed no evidence suggestive of myocarditis.

Case 4. On March 14, a woman aged 43 years with no history of heart disease and no known cardiac risk factors had dizziness and lightheadedness 2 days after vaccination (*1*). On March 16, she had chest pain and dyspnea. Subsequent cardiac catheterization identified a tortuous coronary artery thought to be the cause of her anginal symptoms.

Case 5. A man aged 60 years with a history of hypertension, hyperlipidemia, exertional chest pain, and a family history of CAD had onset of chest pain while playing tennis 4 days after smallpox vaccination and reported to an ED (*2*). Right coronary artery occlusion was diagnosed, and an angioplasty was performed. He was discharged after a 2-day hospitalization.

Case 6. A male civilian federal employee aged 45 years, who had a history of hypertension and who was vaccinated once as a child, was vaccinated on January 23. On February 9, he had fever, chills, malaise, and chest pain. He was hospitalized for 1 day and treated with nonsteroidal anti-inflammatory drugs and prednisone. Electrocardiogram indicated ST segment changes and global J point elevation. His creatinine phosphokinase was reported as mildly elevated at 223 IU (normal range: 55–170 IU), and echocardiography and thallium studies were normal. Myopericarditis was diagnosed. After discharge, the patient was continued on prednisone.

Case 7. On March 14, a woman aged 45 years who was revaccinated on February 26 had myocarditis; the patient had a history of hypertension treated with an angiotensin converting enzyme (ACE) inhibitor (*1*). Approximately 2 weeks before vaccination, she had onset of influenza-like illness (ILI) with fever, chills, myalgia, malaise, cough, and pleuritic chest pain and missed 1 week of work. On February 28, she had sharp left shoulder pain followed by nonexertional chest pain that improved but did not resolve completely with nonsteroidal anti-inflammatory drugs. On March 3, she complained again of dyspnea and exertional chest pain and was hospitalized the next day. On March 5, an echocardiogram demonstrated decreased left ventricular function, left ventricular wall motion abnormality, and a small pericardial effusion. Cardiac catheterization found no evidence of coronary artery disease. Myocarditis was diagnosed. On March 6, the patient was discharged, and her symptoms improved after treatment with an increased dose of ACE inhibitor, addition of a low-dose beta blocker, and NSAIDS. The antecedent ILI and chest pain before vaccination suggests a nonvaccinia infectious etiology.

As of March 23, a total of 10 cases of myocarditis and/or pericarditis have been identified among approximately 225,000 primary vaccinees in the military smallpox vaccination program. All had onset of chest pain 6–12 days following vaccination and all had clinical, laboratory, electrocardiographic, and/or echocardiographic evidence of myocardial and/or pericardial inflammation. None of the cases was clinically severe, and all patients recovered fully and returned to active duty. No cases of myocarditis or pericarditis were detected among approximately 100,000 persons in the military program who were revaccinated.

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Editorial Note: Myocarditis and pericarditis following smallpox vaccination have been reported (*3,4*). The majority of reports were from Europe and Australia, where a more virulent vaccine strain was used, but myopericarditis is not a well-recognized complication following vaccination with the strain of vaccinia being used in the United States (i.e., the New York City Board of Health vaccinia strain, DryVax® [Wyeth Laboratories Inc., Marietta, Pennsylvania]). Data from the military smallpox vaccination program are consistent with a causal association between vaccination and myopericarditis, although this association is not proven.

Other coronary events, including angina and myocardial infarction, have not been previously associated with smallpox vaccination (*5,6*). The relation between smallpox vaccine and the coronary events observed in the civilian vaccination program is unclear.

The frequency of coronary heart disease in the general population makes it difficult to determine if a serious coronary event following vaccination is coincidental or associated with vaccination. The civilian smallpox vaccination program might differ from historical experience because more older patients with underlying heart disease and cardiac risk factors (e.g., hypertension and diabetes mellitus) might be receiving vaccinations. In addition, because current diagnostic tests, including cardiac enzymes and echocardiography, are more sensitive for diagnosing myocardial infarction than previous methods, more events might be detected than were previously observed.

Cardiac-associated death following smallpox vaccination, although extremely rare, has been reported in Europe and Australia and has been thought to be associated with myocarditis (*7,8*). However, in the United States, a death-certificate study of vaccinia-associated deaths conducted during 1959–1966 and 1968 did not identify any deaths associated with cardiac complications (*9*).

Because of the substantial numbers of persons vaccinated in the civilian program, a small number of deaths following vaccination are expected to occur. Of the 25,645 persons vaccinated in the civilian program, age data are available for

14,438. By using the age distribution for these persons, using year 2000 age-specific death rates from all causes (*10*), and assuming that the age distribution is the same for persons whose age is unknown, 2–3 deaths are expected to occur within 3 weeks of vaccination among persons aged 45–54 years and an additional 2–3 deaths among vaccinees aged 55–64 years. Among vaccinees aged 45–64 years, 1–2 cardiac-associated deaths are expected to occur within 3 weeks of vaccination.

Because of the reports of myopericarditis and other cardiac adverse events, CDC and DoD are issuing a supplement to the smallpox vaccine information statement, disseminating information to partners and clinicians, and developing strategies to assess prospectively the incidence and potential causal association of cardiac events among vaccine recipients.

Because a causal relation between smallpox vaccination and serious cardiac events cannot be excluded, CDC recommends as a precautionary measure that persons with known cardiac disease with or without symptoms be excluded from vaccination. As more information becomes available, this recommendation might be revised.

Persons receiving smallpox vaccine should be informed that myopericarditis might be associated with smallpox vaccination and that they should seek medical attention if they develop chest pain, shortness of breath, or other symptoms of cardiac disease after smallpox vaccination. For suspected adverse cardiac events among smallpox vaccine recipients, providers should consult with a cardiologist to ensure appropriate diagnostic studies are conducted to facilitate diagnosis and treatment.

Health-care providers needing assistance evaluating a smallpox vaccinee with a serious adverse event should contact their state health department or CDC's Clinician Information Line, telephone 877-554-4625. This information line, staffed by nurses 24 hours a day, 7 days a week, is a source for general smallpox clinical adverse event information and for assistance with adverse event reporting.

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Rapid Assessment of Tuberculosis in a Large Prison System — Botswana, 2002

Prisons are settings in which tuberculosis (TB) transmission occurs, and TB rates in prisons are often five to 10 times higher than national rates (*1*). Data on the prevalence of TB in prisons in Africa are limited; however, studies from Malawi, Ivory Coast, and Tanzania that used active screening found TB rates ≥10 times higher than national rates (*2–4*). During 1989–2001, TB rates in Botswana increased threefold, from 199 cases per 100,000 population to 620 (Botswana National TB Program, unpublished data, 2002). This increase has been associated with the human immunodeficiency virus (HIV) epidemic (*5*). In Botswana, prisoners are not screened routinely for TB. To determine the prevalence of TB and drug-resistant TB in the Botswana prison system and to improve future screening for TB among prisoners and guards, CDC, in collaboration with the Botswana Ministry of Health and the Division of Prisons and Rehabilitation, screened prisoners and guards at four prisons during April–May 2002. This report summarizes the results of the survey, which indicate a high point prevalence of TB among prisoners in Botswana of 3,797 cases per 100,000 population and support the need for improved screening.

New and existing pulmonary TB cases among prisoners aged ≥16 years and all guards at the four locations in the capital city (Gaborone) prison system were asked to complete an active case-finding questionnaire-based survey. Persons who consented to screening were interviewed privately to ascertain demographic characteristics, prison incarceration or work history, previous medical history, and whether symptoms consistent with pulmonary TB were present. Persons who reported a current cough were asked to provide three separate expectorated sputum samples, which were sent to the national TB laboratory for sputum smear microscopy (all specimens) and mycobacterial culture (the first two specimens). Drug susceptibility testing (DST) for first-line drugs (isoniazid, rifampin, ethambutol, and streptomycin) was performed on one isolate per patient. Sputum was not obtained from those without cough. Persons who reported a cough but were unable to produce sputum were scheduled for chest radiographs, which were